(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date 18 December 2003 (18.12.2003)

PCT

(10) International Publication Number WO 03/103629 A1

(51) International Patent Classification⁷: A61K 9/00, 47/26, 47/38, 47/36

(21) International Application Number: PCT/IB03/02446

(22) International Filing Date: 4 June 2003 (04.06.2003)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

P-200201440

10 June 2002 (10.06.2002) ES

(71) Applicant (for all designated States except US): LABO-RATORIOS VITA, S. A. [ES/ES]; Av. Barcelona, 69, E-08970 Sant Joan Despi (ES).

(72) Inventor; and

(75) Inventor/Applicant (for US only): SEGADO FER-RAN, Javier [ES/ES]; C. Mallorca, 620, 4° 2°, E-08026 Barcelona (ES).

(74) Agents: PONTI SALES, Adelaida et al.; C. Consell de Cent, 322, E-08007 Barcelona (ES).

- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),

European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

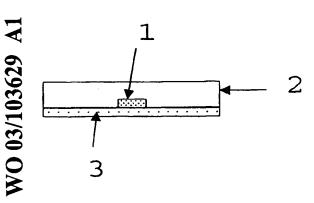
- as to the identity of the inventor (Rule 4.17(i)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)
- of inventorship (Rule 4.17(iv)) for US only

Published:

with international search report

[Continued on next page]

(54) Title: ORALLY DISINTEGRATING TABLETS AND PROCESS FOR OBTAINING THEM.



(57) Abstract: The tablets comprise: at least 59.5% spray-dried mannitol; active ingredient below or equal to 10%, where at least 90% in weight of the active ingredient has a particle size below 100 μm; microcrystalline cellulose 10-18%, with an average particle size of 50 μm and where at least 99% in weight of microcrystalline cellulose has a particle size below 250 μm; sodium croscarmellose 1-4%; and a lubricant agent 0.5-2%; where, unless specified otherwise, the percentages are expressed in weight of the total weight of the tablet. And also a process comprising: sieving and mixing of components except for the lubricant agent; mixing of all components; and direct compression of the final mixture. The tablets of the invention give lower disintegration times as well as good perception on the tongue after disintegration, and overcome the problem of insufficient mechanical resistance for packaging and transport operations.